

## Biocon gets its first generic formulation approval in EU

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Biocon Ltd., Asia's premier biopharmaceuticals company, announced today that it has received European approvals for its Rosuvastatin Calcium 5 mg, 10 mg, 20 mg and 40 mg tablets, a generic equivalent of Crestor tablets, indicated for hyperlipidemia or mixed dyslipidemia. This first generic formulations approval in the regulated markets marks an important milestone in Biocon's small molecules strategy of forward integration from APIs to finished dosages.

The approval for Rosuvastatin Calcium, through decentralized procedure will open the doors for Biocon to over 15 European countries and will enable the company to address \$1.2 billion opportunity, starting FY17. Biocon was the first generic company to receive a Certificate of Suitability (CEP) for Rosuvastatin Calcium API from the European Directorate for the Quality of Medicines (EDQM). CEP certification indicates that an API is suitable for use in medicinal products in the EU.

Biocon Chairperson & Managing Director Kiran Mazumdar-Shaw said: "This is indeed a proud moment for Biocon's Small Molecules business. This approval paves the way for Biocon to launch Rosuvastatin Calcium tablets in several European countries. We plan to collaborate with regional partners in the near term to provide access to this affordable generic and thus help patients and governments to bring down their healthcare spends."

Dr. Arun Chandavarkar, CEO and Joint Managing Director, Biocon said: "The European approval for Biocon's generic version of Rosuvastatin Calcium underscores Biocon's unique strengths in the chronic therapies space and our compliance with global standards that enable us to achieve the highest quality standards for all our products. It augurs well for this nascent business, which will be one of our growth drivers in the coming years."

Biocon aims to rev up its generic formulations business with a target of 20-25 filings over the next few years. Its new potent oral solid dosage formulations facility coming up in Bengaluru will enable this business expansion. The company is also working on dossiers to introduce these formulations in emerging markets where regulatory clearances are primarily based on approvals given by regulators in the US / EU.